IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **Wave 4 cases listed in Exhibit A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF MICHAEL FIEGEN, M.D.

Plaintiffs respectfully request that the Court preclude defense expert Michael Fiegen M.D., from giving opinions on (1) the adequacy of the subject product warnings and instructions for use ("IFU"), (2) the safety and efficacy of the subject products based on his own clinical practice; and (3) the design or safety of the subject transvaginal mesh products.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues

in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Fiegen from giving the opinions referenced above because he is not qualified to opine on those issues and has not done the necessary research to produce opinions that can be reliably applied to this case. Dr. Fiegen produced one 22-page report addressing four products: TVT-Retropubic mechanical cut mesh kit, TVT-Retropubic laser cut

mesh kit, TVT-Obtuator mechanical mesh kit and TVT-Obturator laser cut mesh kit. The reports contain the same general opinions/statements about all four products:

- Defendants' products at issue are not defective; they were reasonably safe for their intended uses; and the benefits of Defendants' product outweigh the risk of using the product. (*See* Report, attached as Exhibit B, at 23)
- The IFU and/or the warnings concerning Defendants' subject product are adequate and allow for the safe use of the device. (*See* Report, attached as Exhibit B, at 22)

The first bullet point relates to Dr. Fiegen's attempt to bolster his design defect opinion based on his own experience as to the safety and efficacy of Defendants' products. As discussed in greater detail below, this is Dr. Fiegen's attempt to backdoor into evidence an improper and unsupported opinion on his personal complication and/or success rate.

For the reasons described below, Dr. Fiegen should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. Dr. Fiegen admits he is not an expert qualified to give opinions on the adequacy of Ethicon's IFUs; thus, his opinions on this issue should be excluded.

This Court has recognized the importance of an expert's admission that he is not an expert in the area of warnings. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). He has never drafted an IFU, never been asked to help draft an IFU, and importantly, no company has ever asked him to review the adequacy of any medical device IFU outside of his opinions at issue in this Motion. Dr. Fiegen testified during his deposition:

Q Have you ever drafted Instructions For Use for transvaginal mesh products?
A No. No, I have not.
Q Have you ever been asked by any company to help draft Instructions For Use for any medical device?
A No. No, I have not.

(Fiegen Deposition, Ex. C, at 14:13-18)

Q Have you ever been asked by any regulatory agency to review the adequacy of Instructions For Use for a medical device?
A No, I have not.
Q And outside of your work related to your report that you have issued in this litigation, has any medical device company ever asked you to review the adequacy of their Instructions For Use for a product?
A No, they have not.
Q And we talked earlier today about the feedback that you provided to Ethicon in your early use of the TVT retropubic device that involved comments that you gave to Ethicon about the trocars and the tensioning of the mesh.
Did Ethicon ever ask you to provide any feedback about the Instructions For Use, specifically what risks were included in the Instructions For Use related to the TVT line of products outside of this report that you've issued?
A No. I was never asked about that or asked for a recommendation, suggestion, anything specific to their IFU.

(Fiegen Deposition, Ex. C, at 69:1-23). When Dr. Feigen was questioned about the one Federal Regulation that was cited in his report to support his opinions regarding the adequacy of the Ethicon IFUs he testified he had never heard of the subject regulation. (Fiegen Deposition, Ex. C, at 70:6-70:21). He also testified he was not aware of what the industry standards were that applied to medical devices. (Fiegen Deposition, Ex. C, at 34:7-18). Importantly, Dr. Fiegen did not review any materials related to Ethicon changing the Ethicon IFUs in 2015 and adding risks the plaintiffs in this litigation have stated should have been in the original Ethicon IFUs all along.

Q (By Mr. Jones) Do you know why Ethicon changed the Instructions For Use, specifically the warning statements in the 2015 TVT IFUs?
A No, I don't -- I don't know. Obviously, I could speculate, but that would be inappropriate. I do not know what conversations occurred within the company, within the senior advisers or their scientists that caused them to move forward with a publication that, in my opinion, again, is particularly redundant.
Q And you haven't read any deposition testimony that has discussed why Ethicon made the change to the 2015 TVT IFUs?
A No, I have not.

(Fiegen Deposition, Ex. C, at 68:12-25).

For the reasoning stated by this court on numerous prior occasions, when a witness admits he has no expertise on a subject any opinions on the subject should be excluded. Dr. Fiegen does not have the necessary expertise under Daubert and Rule 702 to give opinions about the sufficiency of warnings in the IFU for Ethicon products and did not review materials

necessary to provide any reliable foundation for his opinions. The Court, therefore, should exclude those opinions.

II. Any statements or opinions from Dr. Fiegen about his personal perceived experience related to the safety and efficacy of the subject products should be excluded because he admitted he does not know them.

Dr. Fiegen should be precluded from testifying about his perceived safety and efficacy rates with the subject products from his own practice, as that information is entirely unsupported by any meaningful statistical information or analysis. This exclusion should include any imprecise general personal complication or success rates, any imprecise patient follow-up rates and any differences in rates between mechanical cut mesh and laser cut mesh. Any idea in Dr. Feigen's mind of his complication rate is also fundamentally unreliable because of his faulty belief that patients always return to their implanting surgeon when complications rise. (Fiegen Deposition, Ex. C, at 135:1-136:25) Dr. Feigen failed to review relevant literature on this subject stating 1) complications can arise years after implant, and 2) patients seek treatment from a physician different from the implant surgeon when complications arise, including literature that has been introduced in multiple trials in this litigation and cited throughout Plaintiffs' expert reports. (Fiegen Deposition, Ex. C, at 135:1-136:25)

In fact, Dr. Fiegen admits he does not track his patients in a registry, does not know the rates of complications in his patients and any complications rates he uses to support his opinions are based on "hope." (Fiegen Deposition, Ex. C, at 14:6-9; 135:1-136:25)

Dr. Fiegen testified as follows:

6	Q Doctor, do you keep a patient registry of the
7	patients that you have implanted transvaginal mesh
8	products in?
9	A No, we do not.

(Fiegen Deposition, Ex. C, at 14:6-9)

Q Of the 2,400 patients that you've implanted a sling in, are you aware of the percentage of those 2,400 women who currently suffer from vaginal pain?
A No, I'm not aware of that percentage. My hope is that it's zero percent that continue to have pain. We only know if they return, and we have a very good follow-up with our patients. And I'm not

Pat L. Beck, Court Reporter

sure if it's the nature of our clinic, if it's our preoperative indoctrination or if it's just the patients themselves who continue to follow up. I maybe should include the approach that we take. Any patient who undergoes surgery through our office will ultimately be contacted within 24 hours after their surgery. They are seen within one week. If we do not see that patient in follow-up within that first week, our office is calling that patient, trying to locate them.

And, again, we work very hard in our office to maintain effective follow-up of our patients so that we know if issues are arising, and if there are late complications we -- again, our hope is that they'll return to our office.

Q And of the 2,400 women that you've implanted a sling in, do you know how many of those patients currently suffer from recurrence of their stress urinary incontinence?
A I don't. Yeah. I don't know that number, I'm afraid. I'm sorry. I don't. It's a very small number, but I can't tell you specifically. I believe it would be less than 1 percent.

MR. JONES: Those are all the questions I have. Thanks again, Doctor.

(Fiegen Deposition, Ex. C, at 135:1-136:25)

Q Do you ever track, in your patients, whether you used a laser cut mesh or mechanical cut mesh when you implant a TVT obturator device?
A No. I have to admit I'm, frankly, never aware, consciously, of whether or not the mesh that I've implanted is a mechanical cut mesh or a laser cut mesh. I simply have seen no difference between the two, and I never ask myself that question when I'm at the point of implanting them.

(Fiegen Deposition, Ex. C, at 20:10-18)

Q All right. Are you aware that when a patient is implanted with transvaginal mesh, thereafter experiences complications potentially associated with the transvaginal mesh, that more often than not they see a physician who did not implant the transvaginal mesh product?
A No, I would not agree with that. I believe the majority of the patients who have experienced complications from their surgical intervention surface early in their recovery and typically will return to the physician who took care of them, at least that's how it is --
Q What do you base that -- what do you base that statement on?
A On my experience.
Q Is that it?
A Well, is that not enough?

(Fiegen Deposition, Ex. C, at 99:7-23)

Because Dr. Fiegen doesn't know his personal success or complication rate with the subject products at issue in this Motion, his personal success or complication rate should be excluded. Plaintiffs have no reasonable way of testing the veracity of Dr. Fiegen's success or

complication "rates," which exist only in his mind and are based on "hope." Because there is no foundation for these opinions they should be excluded just as this Court has done in similar circumstances.

III. Dr. Fiegen should be precluded from giving design opinions because he lacks the necessary knowledge or expertise on the topic and his methodology in reaching his opinion is fundamentally flawed.

Dr. Fiegen states in his report that "The design of the devices is safe and not defective." (*See* Report, attached as Exhibit B, at 23) There are several reasons why Dr. Fiegen should be precluded from giving opinions as to the design and safety of the subject products, including:

- 1) Dr. Fiegen lacks the requisite expertise to opine on such topics (Fiegen Deposition, Ex. C, at 13:25-14:18; 98:15-24)
    - Including never researching or publishing any materials on transvaginal mesh, Burch procedure or pubovaginal slings (Id.)
- 2) Dr. Feigen admits he is not aware of any the industry standards related to the design and safety of the subject devices (Fiegen Deposition, Ex. C, at 34:7-18)
- 3) Although Dr. Fiegen's reliance list states he reviewed depositions of company employees that related to the design and safety of the subject devices, when asked at his deposition he testified he had not even heard of these individuals (Fiegen Deposition, Ex. C, at 71:13-16; 61:8-62:4, 101:9-11; 102:6-21);
    - Including his admission that he should have known who these individuals were. (Id.)
    - And including his admission he could not name a single Ethicon employee in research and development of Ethicon products (Id.)

- 4) Dr. Fiegen has never heard of an important medical society statement discussing the safety, or lack thereof, of the subject devices including a body of literature that established the transvaginal mesh complication classification system (Fiegen Deposition, Ex. C, at 23:16-22);
- 5) Not surprisingly, Dr. Fiegen admits he did not prepare his reliance list. (Fiegen Deposition, Ex. C, at 35:1-7);
- 6) He lacks basic knowledge of the facts of this case, including some addressed in his expert report. (Fiegen Deposition, Ex. C, at 56:19-22)
    - Including testifying he had seen medical literature that reports the mesh frays, ropes and curls when his report says there is no literature that exists. A direct comparison of the statement which appears in his report "The peer-reviewed published medical literature regarding the slings does not discuss these issues…" to his testimony reveals his lack of the basic knowledge of the facts of this case. (Report, Ex. B, at 20; Fiegen Deposition, Ex. C, at 26:9-13)

9	Q Okay. You have reviewed medical journal
10	articles that have concluded that transvaginal mesh
11	for SUI can curl or rope inside of a patient's body
12	after it is placed; correct?
13	A I have.

    - Including stating in his report, "Larger-pore, lighter-weight meshes like Ultrapro have been developed, but did not prove to be feasible in Ethicon's testing." but not even being aware Ethicon had applied for clearance telling the FDA the safety and efficacy had been established with an Ultrapro TVT sling. (Report, Ex. B, at 21; Fiegen Deposition, Ex. C, at 58:18-59:4)

Q Are you aware that Ethicon applied to the FDA for clearance for the use of Ultrapro in a TVT obturator sling?
MR. KOOPMANN: Object to form. Go ahead.
A I'm -- I'm not aware of that.
Q (By Mr. Jones) Okay. So you haven't seen the application Ethicon filed with the FDA to gain clearance for the use of the larger-pore,

lighter-weight mesh, Ultrapro, in the TVT obturator application?
MR. KOOPMANN: Object to form. Go ahead.
A I have not seen that.

- And, finally, including testifying fraying of the mesh was not part of the design when his report cites to materials by Ethicon medical directors that say "Fraying is inherent in the design" (Fiegen Deposition, Ex. C, at 56:19-22)

As far as Dr. Fiegen's expertise in this field, he testified as follows:

Q Doctor, have you published any research related

to transvaginal mesh products?
A No, I have not.
Q Doctor, have you ever performed any studies related to transvaginal mesh products?
A No, I have not.
Q Doctor, do you keep a patient registry of the patients that you have implanted transvaginal mesh products in?
A No, we do not.
Q Doctor, have you performed any research projects on transvaginal mesh devices?
A No, I have not.
Q Have you ever drafted Instructions For Use for transvaginal mesh products?
A No. No, I have not.
Q Have you ever been asked by any company to help draft Instructions For Use for any medical device?
A No. No, I have not.

(Fiegen Deposition, Ex. C, at 13:25-14:18).

Q Have you ever done any type of pathological analysis or pathology analysis on polypropylene mesh?
A No, I have not.
Q Have you ever published any material on the Burch procedure?
A No, I have not.
Q Have you ever published or written anything on pubovaginal sling?
A No, I have not.

(Fiegen Deposition, Ex. C, at 98:15-24).

Q Yes. Other than providing feedback to Ethicon sales representatives about your early use of the TVT retropubic device, is there anything that you want to add related to your experience in designing a medical device?
A No.
Q And do you hold any patents, Dr. Fiegen?
A No, I do not.

(Fiegen Deposition, Ex. C, at 21:9-16).

Q Will you be offering any opinion that Ethicon met industry standards for a medical device company in this litigation?
MR. KOOPMANN: Object to form. Go ahead.
A Isn't that what we're doing right now?
Q (By Mr. Jones) Well, what are the industry standards that you're opining that Ethicon met in this litigation related to -- we'll first start with the design of the TVT and TVT obturator mesh.
A I have to say that I'm not aware of any industry standards that existed before this -- before this product was ever brought to market.

(Fiegen Deposition, Ex. C, at 34:7-18). Dr. Feigen's testimony related to his reliance is below:

Q And did you prepare your reliance list?
A No. No, I did not. Let's see, I want to make sure that I understand. The list of medical literature that we included?
Q Correct.
A No. I did not provide -- I did not create that.

(Fiegen Deposition, Ex. C, at 35:1-7)

Because Dr. Fiegen lacks the expertise and methodology was fundamentally flawed, Dr. Fiegen lacks the required knowledge to give a reliable opinion about the design or safety of the subject devices. As such, he should be precluded from giving any opinions related to design or safety of the subject products.

CONCLUSION

Based on the foregoing, Dr. Fiegen should be precluded from giving opinions on (1) the adequacy of the subject product warnings and instructions for use ("IFU"), (2) the safety and efficacy of the subject products based on his own clinical practice; and (3) the design or safety of the subject transvaginal mesh products.

Dated: April 13, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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